Applicant:

TW

**PATENT** 

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

pplicant: STAHMANN et al.

Examiner:

Unassigned

Serial No.:

10/643,154

Group Art Unit:

3736

Filed:

August 18, 2003

Docket No.:

GUID.103PA

(03-504)

Title:

THERAPY TRIGGERED BY PREDICTION OF DISORDERED

**BREATHING** 

By: Nace M Dottes
Tracey M. Dotter

## RESPONSE TO RESTRICTION/ELECTION OF SPECIES REQUIREMENT

MAIL STOP NONFEE AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Customer No. 51294

Sir:

In response to the Non-Final Office Action dated July 12, 2005 in which a restriction requirement and election of species were made, the claims of Invention I (1-48, 80-99, and 100) are hereby elected with regard to the restriction requirement as between the Invention I and II claims. As such, please cancel the claims of Invention II (49-79 and 101) without prejudice. Applicants, however, traverse the Examiner's requirement for election of species.

In compliance with 35 U.S.C. § 121, Applicants hereby elect, with traverse, the claims readable on Species a (Physiological signal detection) and Subspecies 1 (Respiratory system condition) identified by the Examiner as one of two purported distinct species with ten purported subspecies. Commensurate with the disclosed aspects of the Species a, Applicants believe claims 1-5, 14-48, 80-86, and 88-100 are readable on Species a and Subspecies 1.

Having complied with 35 U.S.C. § 121, Applicants respectfully assert that the Examiner is overzealously and inappropriately applying the provisions of 35 U.S.C. § 121 with regard to the identification of two purported species and ten purported subspecies in the disclosure.

In order for claims to be restricted to different species, such claims <u>must be</u> mutually exclusive (MPEP § 806.04(f)). Claims can be restricted to different species only where one claim recites limitations which, under the disclosure, are found in a first species but <u>not</u> in a second, while a second claim recites limitations disclosed <u>only for</u> the second species and <u>not</u> the first. Claims restricted to different species must recite the mutually exclusive characteristics of such species.

Applicants respectfully assert that the Examiner's identification of species in the Office Action is in error and does not comply with the mutual exclusive requirement of MPEP § 806.04(f). Species are always the <u>specifically different</u> embodiments. MPEP § 806.04(e) Claims to be restricted to different species must be mutually exclusive. MPEP § 806.04(f). The Species identified the Examiner, Species a (Physiological signal detection) and Species b (Non-physiological signal detection) are not specifically different embodiments because the claims drawn to these species are not mutually exclusive. For example, Claim 4 recites physiological signal detection which is the defining characteristic of Species a and Claim 10 recites non-physiological signal detection which is the defining characteristic of Species b. Claim 4 and Claim 10 do not recite mutually exclusive limitations. These limitations are not mutually exclusive because they can co-exist and both are illustrated in the embodiment depicted in Figure 2 and the embodiment depicted in Figure 6..

For example, regarding the embodiment depicted in Figure 2, Applicants' disclosure at page 13 line 19 – page 14 line 11 clearly states that the system illustrated by Figure 2 may detect physiological conditions AND contextual (non-physiological) conditions:

"The system may use patient-internal sensors 210, implanted within the body of the patient to detect physiological conditions... The system may use patient-external sensors 220 to detect physiological or contextual conditions... Signals from one or more of the patient-internal sensors 210, patient-external sensors, and patient input devices 230 may be coupled to the disordered breathing prediction engine"

Both detection of physiological signals and detection of non-physiological signals can be simultaneously present in one embodiment and thus are not mutually exclusive. Because

the claim limitations associated with the purportedly distinct species are not mutually exclusive, the Examiner's identification of separate Species a and Species b is in error.

In addition, the Applicants respectfully assert that the Examiner's identification of subspecies in the Office Action is also in error and does not comply with the mutually exclusive requirements of MPEP § 806.04(f). For example, claim 5 recites the characteristic defining Subspecies 1 of Species a (Respiratory system condition), claim 6 recites the characteristic defining Subspecies 2 of Species a (Cardiovascular system condition), claim 7 recites the characteristic defining Subspecies 3 of Species a (Nervous system condition), claim 8 recites the characteristic defining Subspecies 4 of Species a (Blood chemistry condition), and claim 9 recites the characteristic defining Subspecies 5 of Species a (Muscle system condition). Each of these limitations could coexist in one claim, therefore these claims do not present limitations that are mutually exclusive as required by MPEP § 806.04(f).

For example, with respect to the embodiment illustrated by the Figure 6, the system can include, "implanted cardiac electrodes 631 and other patient-internal sensors 680, such as the patient-internal sensors illustrated in Table 1." (specification, page 30, lines 20-22). Table 1 lists sensors for detecting respiratory system conditions, cardiovascular system conditions, nervous system conditions, blood chemistry conditions, muscle system conditions cardiac system conditions, and more. It is clear from the description of the embodiment depicted in Figure 6, that any or all of these conditions may be detected. Subspecies 1, 2, 3, 4, and 5, do not represent specifically different embodiments. A similar argument may be made for Subspecies 6 and 7 of Species a and Subspecies 1, 2, and 3 of Species b. Because the claim limitations associated with the purportedly distinct Subspecies are not mutually exclusive, the Examiner's identification of separate Subspecies is in error.

Applicants respectfully assert that the Species election requirement and the Subspecies election requirement is in error and necessitates withdrawal. The mutually exclusive requirement of MPEP § 806.04(f) is not met.

In the above-made arguments, Applicants are contesting the propriety of the Examiner's election of species restriction requirement. Applicants, however, are not traversing on the ground that the "species" identified by the Examiner are not patentably distinct, but rather

are asserting that the basis for requiring election between species and subspecies is not supported.

Applicants respectfully remind the Examiner that, upon allowance of a generic claim, Applicants are entitled to consideration of claims to additional species and subspecies, including those identified by the Examiner, pursuant to 37 CFR 1.141.

Applicants respectfully request that the Examiner reconsider the appropriateness of the 2-way species election requirement and 10-way subspecies election requirement. Applicants further request that the Examiner seriously consider the undue burden and expense that would be borne by Applicants should the requirement be maintained. Reconsideration and withdrawal of the restriction requirement as to the election of species and subspecies are, therefore, respectfully requested.

If the Examiner has any questions or comments, a telephone call to the Applicants' Representative at the number provided below is invited.

Respectfully submitted,

Hollingsworth & Funk, LLC 8009 34<sup>th</sup> Avenue South Suite 125 Minneapolis, MN 55425 (952) 854-2700 x 13

Date: August 12, 2005

Clara Davis Reg. No. 50,495